DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 6, 2014

Alliance Partners, LLC
% Ms. Kellen Hills
Quality & Regulatory Consultant
Orchid Design
4600 East Shelby Drive
Memphis, Tennessee 38118

Re: K141993
Trade/Device Name: Nakoma ACP System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 8, 2014
Received: August 11, 2014

Dear Ms. Hills:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141993

Device Name
Nakoma ACP system

Indications for Use *(Describe)*
The Nakoma ACP System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The Nakoma ACP System is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusion in patents with the following indications:

- Degenerative Disk Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis or scoliosis)
- Pseudoarthrosis
- Failed previous fusions
- Spondylolisthesis
- Spinal Stenosis

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

[As Required by 21 CFR 807.92]

(a)(1) Submitted By:

Alliance Partners, LLC
14206 Northbrook Dr.
San Antonio, TX 78232
Phone: 210-314-2525
Fax: 210-314-2524

Date: November 6, 2014

Contact Persons
Primary: Kellen Hills (Orchid Design Consulting)
Secondary: Frank Morris (Alliance Partners, LLC)

(a)(2)

Proprietary Name:	Nakoma ACP
Common Name:	Anterior Cervical Plate
Classification Name and Reference:	21CFR 888.3060 – Spinal intervertebral body fixation orthosis
Product Code:	KWQ

(a)(3) Predicate Devices:
Primary: Custom Spine-REGENT (K091134)
Secondary: Aesculap-QUINTEX (K100243)

(a)(4) Device Description:

The Nakoma Anterior Cervical Plating (ACP) system is used for spinal fusion surgery to provide support and structural stability. The system consists of a variety of plates and screws, all of which are manufactured from titanium alloy per ASTM F136. Instrumentation necessary for proper implantation is also included.

The plates are available in a range of lengths in Levels 1-5 and feature windows to aid in visualization and locking clips to assist in screw retention. The screws are available in multiple lengths and diameters, feature self-tapping and self-drilling designs and are able to be placed on-axis and at various angles (15° medial/lateral, 10° cephalad/caudal).

The purpose of this submission is to gain initial marketing authorization in the United States.

(a)(5) Indications for Use:

The Nakoma ACP System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The Nakoma ACP System is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusion in patents with the following indications:

- Degenerative Disk Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis or scoliosis)
- Pseudoarthrosis
- Failed previous fusions
- Spondylolisthesis

• Spinal Stenosis

(a)(6) Comparison of Technological Characteristics:
The fundamental scientific technology, materials of construction and mechanism of operation is the same between the subject Nakoma ACP and predicate Regent ACP device. Both are intervertebral fusion devices, designed to provide support and stabilization in order to achieve fusion between adjacent vertebrae. Both subject and predicate devices are made from titanium alloy and incorporate retention clips and multiple screw options. Both subject and predicate devices offer plates and screws in comparable size ranges. Both devices utilize instrumentation common to spinal fusion surgery.
Additionally, Aesculap's QUINTEX system was used as a dimensional predicate for the Level 5 plates of the subject Nakoma ACP system.

(b)(1) Non-clinical testing:
Testing in accordance with ASTM F1717 (i.e., static compression, static torsion, dynamic compression) was conducted and the subject devices were found to perform equivalently to the predicates.

(b)(2) Clinical testing:
Clinical testing was not required to demonstrate substantial equivalence in this premarket notification.

(b)(3) Conclusions:
Based on the information provided in this premarket notification and the details specified in FDA guidance "Spinal System 510(k)s", we believe that the subject Nakoma ACP system is as safe, as effective, and performs as well as or better than the predicate devices.